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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,298	07/02/2001	Steven M. Ruben	PZ035P1C1	4425
22195	7590	11/20/2003	EXAMINER	
HUMAN GENOME SCIENCES INC 9410 KEY WEST AVENUE ROCKVILLE, MD 20850			O HARA, EILEEN B	
		ART UNIT	PAPER NUMBER	
		1646		

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/895,298	RUBEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Eileen O'Hara	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a)  The period for reply expires 6 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on 21 October 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3.  Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 25-37, 40-44, 47-51, 54-58, 61-74.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8.  The drawing correction filed on \_\_\_\_\_ is a) approved or b) disapproved by the Examiner.
9.  Note the attached Information Disclosure Statement(s) ( PTO-1449) Paper No(s). \_\_\_\_\_.
10.  Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): rejection of claims under 35 U.S.C. 112, first paragraph for written description.

Applicants' assertion that the finality of the Office Action (Paper No. 9) was premature because of new references cited and expanded arguments has been fully considered but not deemed persuasive, because the citation of new references and the arguments presented in the final action were in response to Applicants' arguments, and were not new arguments, and the references were also cited to support the rejection in the non-final office action. Applicants' arguments traversing the rejection under 35 U.S.C. 112 first paragraph for lack of enablement, in that the test for enablement is whether one of ordinary skill in the art can practice the claimed invention without undue or unreasonable experimentation, and that demonstrating statistical certainty or providing statistical evidence/analysis is not a requirement for the patentability of one's invention, has been fully considered but not deemed persuasive, for reasons of record in the previous office actions. Ferrari et al. and Clark et al. were cited to demonstrate that even a relatively small number of patients or tissue or cell samples can be useful in establishing the potential as a cancer marker, but that expression can be highly variable. The instant application does not disclose how many samples were used to determine expression. If only one or a few samples for each tissue type were analyzed, there is a high probability for false-negative and false-positive results, which was demonstrated by Clarke et al. in the variability of expression of the PIP protein in both cancerous and normal tissues. There is no information in the specification as to how many tissue samples were analyzed or the degree of expression in cancer tissue relative to normal tissue. The art teaches that expression of genes in cancerous or normal tissue from different sources can be highly variable. Because of the lack of information on number of samples analyzed, the instant specification does not enable the use of the protein of SEQ ID NO: 83 as a cancer marker, and the rejection is maintained.



**LORRAINE SPECTOR  
PRIMARY EXAMINER**